

Engineering Evaluation of Nuclear Powered Pacemakers as Special Form Radioactive Material

by

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Problem

Approximately 1600 nuclear powered cardiac pacemakers and/or battery assemblies have been located across the United States which are eligible for recovery by the Off-Site Source Recovery Project (OSRP) Team at Los Alamos National Laboratory (LANL). These devices typically contain approximately 3 to 8 Curies (0.2 to 0.5 grams) of Plutonium (Pu)-238 as the heat source for the batteries. All of these devices were manufactured to specifications contained in "Interim Guide to the Design and Testing of Nuclear Powered Cardiac Pacemakers", USAEC, March 26, 1974. The testing criteria for these devices, in order to ensure the safety of the individual in which the device was implanted, was extremely rigorous.

To facilitate recovery and storage of these devices by the OSRP, a practical and compliant method of packaging and transportation is needed. Under US Department of Transportation (DOT) requirements for radioactive material (RAM) transport, no more than $5.41\text{E-}3$ Curies, which roughly corresponds to $3.14\text{ E-}4$ grams of Pu-238 can be shipped in a Type A container. This A_2 Value from 49CFR173 is the Type A quantity limit for normal form Pu-238. This means that transportation of a single normal form pacemaker or battery assembly in a Type A shipping container is not allowed.

If the fuel capsules of pacemakers and battery assemblies can be qualified as special form under 49CFR173.469, then the quantity that could be transported in a Type A container (A_1 Value from 49CFR173) increases to 54.1 Curies, which corresponds to 3.14 grams, or roughly 15 pacemaker or battery assemblies. This would permit all of the known pacemaker or battery assemblies to be consolidated into approximately 105 standard pipe overpack component (POC) assemblies for transport. The POC is a Type A package approved for waste disposal at the Waste Isolation Pilot Plant (WIPP) in Carlsbad, New Mexico.

Background

Cardiac pacemakers were manufactured by a number of companies, including ARCO (Permagrain), Medtronic (Laurens-Alcatel), Gulf General Atomic, Cordis (Telektronic, Accuffix), American Optical, and Biocontrol Technology (Coratomic). The battery assembly, which is the component within the pacemaker that contains the Pu-238 heat source, was also made by a diverse group of companies, including Numec, Hittman Nuclear Battery Corporation (sources from Battelle Columbus Research Labs (BCRL)), CIT-Alcatel, Parkwell Laboratory, UKAEA,

and others. Fortunately, all of these different nuclear powered pacemakers are similar in size and function, all having been designed to meet the requirements specified in the US Atomic Energy Commission (AEC) "Interim Guide to the Design and Testing of Nuclear Powered Pacemakers," cited above.

Solution to Problem

The DOT requires, in 49CFR173.476, that

"Each offeror of special form Class 7 (radioactive) materials must maintain on file for at least one year after the latest shipment, and provide to the Associate Administrator for Hazardous Materials Safety on request, a complete safety analysis, including documentation of any tests, demonstrating that the special form materials meets the requirements of 173.469....."

Some manufacturers of pacemakers and/or battery assemblies qualified their heat sources as special form. The special form certificate for the Coratomic Type X source, USA/0383/S, is provided as Attachment A. However, all manufacturers complied with the same AEC design and testing requirements which specified the conditions of the tests. Since only some of the AEC pacemaker designs were qualified as special form, but all were made to the same specifications, it follows that, by comparing the testing under the AEC requirements to the testing requirements in 49CFR469, a safety analysis which demonstrates equivalency of testing may be completed.

Comparison

This is the approach I recommend for qualifying pacemakers and/or battery assemblies as special form, regardless of the manufacturer. A point by point comparison of the actual testing methodologies will be made, comparing the stringency of each test. Then, a matrix of actual test data for each type of pacemaker will be developed to show the actual test conditions used by the individual manufacturers. This matrix will enable the evaluator to determine the degree of conservatism inherent in the testing of these devices. Table 1 summarizes and compares the testing criteria from the AEC document cited above and the criteria from 49CFR173.469. A complete listing of the two sets of requirements is provided in Attachment B. While the test names vary, the purpose of these tests is very similar in their examination of capsule integrity under the various test conditions. The testing requirements for the pacemaker devices were much more rigorous than those for special form testing due to the potential for immediate hazard to humans, i.e. these medical devices were intended to be implanted in human beings and to remain there for many years at a time.

Table I. Comparison of two sets of testing criteria

Test Criteria	49CFR 173.469¹	AEC Interim Guidance²
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Impact Test	9 m drop	50 m/s
Percussion Test	1 drop of a 1.4 kg billet dropped from 1 m	None
Crush Test	None	50 times a 2200 lb _f static load on the source capsule with random orientation
Temperature	800°C for 10 min, quenched	800°C for 30 min, quenched
Temp - Crush	None	800°C for 30 min, quenched followed by 1000 kg crush
Temperature - Pressure	None	Bursting pressure at 600°, 1000° and 1300°C.
Temperature - Cremation	None	1300°C for 30 min.
Leaching/Corrosion	Distilled water at 50°C for 4 hr.	Sea water w/wo oxygen for 1 yr.

Discussion

A point by point comparison of the DOT and AEC sets of testing criteria establishes the following differences:

Impact Test: The 9 m drop of the DOT test imparts a terminal velocity of about 13 m/s. The AEC Interim Guidance test velocity is 50 m/s on impact. The capsule terminal test velocity is 3.8 times greater for the AEC Interim Guidance test than for the DOT test. Therefore, the AEC Interim Guidance test is more stringent.

Percussion/Crush Tests: The mechanical strength (stress/strain) of the capsule was tested in both testing scenarios. A percussion test is required for the DOT evaluation, but not for the AEC Interim Guidance testing. A static crush test is required for the AEC Interim Guidance testing, but not for the DOT test. The equivalency of these two mechanical tests can be evaluated by performing an engineering analysis to determine the normalized stress applied by both test methods.

The percussion test specified in the DOT regulations can be analyzed as an impulse of force applied to the sealed source. The force of the impulse (**F_{impulse}**) is equal to:

$$\mathbf{F_{impulse} = (m \times V)/(g \times \Delta t)}$$

where

m is the mass of percussion test billet (1.4 kg or 3.08 lb)

V is the velocity of the falling billet (14.6 ft/s)

g is the gravitational constant (32.2 ft/sec²)

Δt is the contact time (estimated to be 1 ms (0.001 s))

$$\mathbf{F_{impulse} = (3.08 \text{ lb} \times 14.6 \text{ ft/s}) / (32.2 \text{ ft/sec}^2 \times 0.001 \text{ s}) = 1400 \text{ lb}_f}$$

The resulting 1400 lb_f kinetic load can be compared directly to the 2200 lb_f static load used for the AEC Interim Guidance test. The AEC test is 57% greater in applied force for each crush test.

When a random orientation of the test specimen is selected for the crush test as described in the AEC Interim Guidance, the load is applied 50 times to the test specimen. Therefore, the AEC Interim Test Guidance is more stringent than the DOT special form test requirements.

Temperature: The initial 800°C soak is 3 times longer in the AEC Interim Guidance test than in the DOT test. The AEC Interim Guidance requires that three additional thermal related tests be conducted. One is to determine whether high temperature weakens the structural integrity of the containment. The second is to determine whether raising the capsule to a high temperature will cause the containment integrity to be challenged by elevated internal pressures. The third test at 1300°C simulates the maximum temperature environment a cadaver undergoing cremation would experience. Together these additional thermal tests make the AEC Interim Guidance tests much more stringent than the DOT special form test requirements.

Leaching/corrosion: The DOT leaching test lasts 4 hrs at 50°C in distilled water. The AEC test lasts 8,760 hr (1 yr). The AEC test is really a corrosion test, as well, to determine if the outer capsule will be attacked significantly after a year in a solution similar to body fluids (i.e. sea water). Detection of any transported activity would require violation of both shells of the fuel capsule before any leaching could occur. Therefore, the AEC Interim Guidance Test is far more stringent than the DOT special form test.

From comparisons between the two sets of test criteria, the tests required by the AEC Interim Guidance document are much more stringent than those required for DOT special form testing.

Results

Actual test data for cardiac pacemaker fuel capsules are compared to the required AEC² Interim Guidance testing in Table II. The results of these tests are not presented here, only that the test specimens were tested under the stated conditions and passed the testing requirement. This is done to develop a basis for estimating any additional levels of conservatism instilled by the manufacturer's actual testing. The testing data in Table II were provided to OSRP in the form of test reports by the vendors currently holding inventories of pacemakers. Note that two pacemaker fuel capsules (Medtronic and Biocontrol) were certified as special form by the manufacturers. The Biocontrol (formerly Coratomic) pacemaker testing information is included in Table II as the only US certified (USA/0383/S) special form sealed source.

Table II. Comparison of Manufacturers Testing to Required AEC Interim Guidance Testing

Mfg.		ARCO³ (Perma -Grain)	Medtronic⁴	General Atomic⁵	Cordis⁶ (Telektronic, Accufix)	American Optical⁷	Biocontrol Technologies (Coratomic)⁹
Model		NU-5	Laurens-Alcatel 9000	(Mk A Mk B)	184A & 184B	281343	Coratomic ⁹ CP-100 & CP-101, Pulsar
Battery (source)		(Numec)	(CIT-Alcatel)	(UKAEA)	Hittman ⁸ NB-200 (BCRL)	Hittman ⁸ NB-200 (BCRL)	(Parkwell Lab.)
Test	Requirement²						
Impact	50 m/s	56 – 74 m/s	50 m/s	No Data	50 m/s	See Cordis data	>50 m/s
Crush	1,000 kg	19,000 kg	5,000 kg	1,800 kg or greater	1,250 kg	See Cordis data	1000 kg
Temp.	800°C, 30 min	1370°C 2.2 hr	800°C, 30 min	850°C 3 hr.	850°C, 30 min	See Cordis data	830°C 30 min
Temp.-Crush	800°C, 30 min. /1000 kg	800°C, 30 min. /1000 kg	800°C, 30 min. /1000 kg	No Data	800°C, 30 min. /1000 kg	See Cordis data	830°C 30 min/ 1000 kg
Temp. - Pressure	No failure from gas pressure at high temp.	Sf 2 2000 yr.	800°C Sf 3.8 150 yr.	850°C, 10 hr. 25 yr.	1300°C Sf 4 @ 41 yr.	See Cordis data	1300°C sf 4.3 @115 yr
Temp. - Cremation	1300°C, 30 min. 10 yr.	1370°C, 2.2 hr, 150 yr.	1300°C, 30 min.	No Data	1300°C 90 min.	See Cordis data	1300°C 90 min.
Corrosion	Lin. Corrosion < 1 um/yr.	No corrosion	no corrosion for 1 st yr.	No Data	No corrosion	See Cordis data	<1 mil/ 1000 yr.

^{2,3,4,5,6,7,8,9,10} See Reference List at end of document

Reported data for Gulf General Atomic (GA) fuel capsules are incomplete. This occurred because the GA report actually preceded publication of the AEC Interim Guidance by 1.2 years. The GA data did not specifically include impact testing and corrosion data. GA impact test data is evaluated below by engineering analysis to determine if the force applied to the capsule in other tests sufficiently stressed the capsule to bound any potential damage from the impact test.

The force of the impulse (F_{impulse}) applied to the capsule by the impact test is equal to:

$$F_{\text{impulse}} = (m \times V)/(g \times \Delta t)$$

where

m is the source capsule mass (2.65 g or 0.006 lb.)

V is the velocity of the hurtling source (50 m/s or 164 ft/s)

g is the gravitational acceleration (32.2 ft/sec²)

Δt is the contact time (estimated at about 1 ms (0.001 s))

$F_{\text{impulse}} = (0.006 \text{ lb} \times 164 \text{ ft/s}) / (32.2 \text{ ft/sec}^2 \times 0.001 \text{ s}) = 31 \text{ lb}_f$

F_{impulse} applied to the GA fuel capsule in the impact test is equal to about 31 lb_f. This can be compared to the minimum force applied to the capsule in the crush test of 2200 lb_f. The crush test applies a minimum of 70 times more force and, in fact, the GA crush test was repeated at greater than 126 times the force applied by the impact test. It is my opinion that the GA capsule will readily pass the impact test.

For those manufacturers for which no data is provided in Table II, an analysis and comparison of other technical data will be made. A table of technical data covering the materials of construction and relative sizes of the fuel capsules and pacemakers is presented as Attachment C.

The corrosion issue for GA can be analyzed by comparing materials of construction for the fuel capsule (see Attachment C). Hastelloy C-276 was selected as the fuel capsule material for its resistance to oxidation and corrosion. ARCO and Cordis tested their Hastelloy C-276 fuel capsules and reported no corrosion for the testing period. Since the GA capsule (UKAEA Mk A & Mk B) is fabricated from the same materials, using similar techniques, it is logical to conclude that the loaded fuel capsule would show minimal or no corrosion in a sea water test environment.

The testing data for the American Optical pacemaker is not available. However, the Pu-238 sealed source is contained in a Hittman Model NB-200 nuclear battery. This is the same Model NB-200 that is used in the Cordis pacemaker. The testing of the Cordis Pacemaker was documented in a test report that is summarized by the data in Table II. Since the Cordis pacemaker fuel component was tested and passed the required tests, the American Optical fuel component, which is identical to that in the Cordis pacemaker, should also meet the 49CFR test criteria.

Summary

A comparison has been made of the sealed source testing required for DOT special form material and testing outlined in the AEC Interim Guide to Design and Testing of Nuclear Powered Cardiac Pacemakers. The comparison demonstrates that the AEC requirements were much more stringent. Four manufacturers (Cordis, ARCO, Biocontrol, and Medtronic) tested the Pu-238

pacemaker fuel capsules under conditions which met all AEC requirements and exceeded the DOT requirements. General Atomic fuel capsules were not tested for impact and corrosion. The incomplete data in the GA test has been evaluated by engineering analysis. The engineering analysis indicates that the General Atomic pacemaker will pass the impact and leaching tests required by 49CFR173.469. The American Optical pacemaker data was not specifically available, however, comparison with identical fuel capsules from the Cordis Pacemaker indicates that these devices meet special form criteria.

Conclusion

Pacemakers manufactured by Cordis, ARCO, Medtronic, American Optical, General Atomics, and Biocontrol (or their parent companies) meet the requirements for special form material under 10CFR173.469.

References

1. 49 Code of Federal Regulation Part 173, sub-part 469, Requirements for Special Form Materials
2. NRC Interim Guide to the Design and Testing of Nuclear Powered Cardiac Pacemakers (formerly AEC Interim Guide..., 3/26/74)
3. Report: ARCO Nuclear Technical Document 032974, April 15, 1974
NRC Device Index No.: NR-8033-D-803-S
4. Technical Report on the Medtronic™ Model 9000 Isotopic Pulse Generator, June 1, 1974
NRC Device Index No.: NR-8104-D-801-S
5. Report: Radiological Safety of Miniature Nuclear Batteries, Gulf General Atomic, Gulf-GA-C10926, January, 1972
NRC Device Index No.: CA309D101S & CA309D102S
6. Report: Cordis Nuclear Omni-Stanisor (model 184A), May 10, 1976
NRC Device Index No.: NR-8042-D-801-S
7. American Optical
See NRC Device Registry No.: NR-975-D-801-S & NR-133-D-101-U
8. Hittman Nuclear Development Corp.,
NRC Device Index No.: NR-MD351D101U
9. Coratomic, Inc., License Application and Surgical Protocol for C-100 Radioisotope Pacer Human Implant Program, Amended September 1, 1974
NRC Device Index No.: NR-874-D-801-S



U.S. Department
of Transportation

Research and
Special Programs
Administration

**IAEA CERTIFICATE OF COMPETENT AUTHORITY
SPECIAL FORM RADIOACTIVE MATERIALS
CERTIFICATE NUMBER USA/0383/S, REVISION 2**

400 Seventh Street, S.W.
Washington, D.C. 20590

This certifies that the source described has been demonstrated to meet the regulatory requirements for special form radioactive material as prescribed in the regulations of the International Atomic Energy Agency¹ and the United States of America² for the transport of radioactive materials.

1. Source Identification - Coratomic Type X source for cardiac pacemaker.
2. Source Description - This nearly spherical source has a diameter of 8.6 mm (0.34 in). The tantalum alloy inner capsule and the platinum-rhodium alloy outer capsule are sealed by inert gas welds. Source is illustrated in Coratomic drawing no. C-4101-17 (attached).
3. Radioactive Contents - Not more than 0.16 TBq (4.27 Ci) of plutonium-238 in the form of a sintered plutonium oxide pellet.
4. Quality Assurance - Records of Quality Assurance activities required by Paragraph 209 of the IAEA regulations¹ shall be maintained and made available to the authorized officials for at least three years after the last shipment authorized by this certificate. Consignors and consignees in the United States exporting or importing shipments under this certificate shall satisfy the requirements of Subpart H of 10 CFR 71.
5. Expiration Date - This certificate expires August 31, 2003.

This certificate is issued in accordance with paragraph 703 of the IAEA Regulations and Section 173.476 of Title 49 of the Code of Federal Regulations, in response to the petition and information dated May 15, 1997 submitted by Biocontrol Technology, Inc., Indiana, PA, and in consideration of other information on file in this Office.

Certified by:


Alan I. Roberts

Associate Administrator for Hazardous Materials Safety

AUG 28 1998

(DATE)

Revision 2 - Issued to extend the expiration date.

1 "Safety Series No. 6, Regulations for the Safe Transport of Radioactive Materials, 1985 Edition, as amended 1990", published by the International Atomic Energy Agency (IAEA), Vienna, Austria.

2 Title 49, Code of Federal Regulations, Parts 100 - 199, United States of America.

Testing Requirements

§49 CFR173.469 *Requirements for special form Class 7 (radioactive) materials*

Impact Test: The specimen must fall onto the target from a height of 9 meters (30 ft) or greater.

Percussion Test: The specimen must be placed on a sheet of lead that is supported by a smooth solid surface, and struck by the flat face of a steel billet so as to produce an impact equivalent to that resulting from a free drop of 1.4 kg (3 lb.) through 1 meter (3.3 ft.).

Heat Test: The specimen must be heated in air to a temperature of not less than 800°C (1475°F), held at that temperature for a period of 10 minutes, and then allowed to cool.

Leach test: (i) The specimen must be immersed in water at ambient temperature. The water must have a pH of 6-8 and a maximum conductivity of 10 micro-ohm per centimeter. (ii) The water and specimen must be heated to a temperature of 50°C \pm 5° (122°F \pm 9°) and maintained at this temperature for four hours. (iii) The activity of the water must then be determined. (iv) The specimen must then be stored for at least seven days in still air at a temperature of 30°C (86°F) or greater. (v). The process in paragraphs (c)(2)(i), (c)(2)(ii), and (c)(1)(iii) of this section must be repeated. (vi) The activity determined in paragraph (c)(2)(iii) may not exceed 2 kBq (0.05 micro-curie).

Testing under the *AEC Interim Guidance Testing (March 26, 1974)*

Impact: The test shall be performed by projecting the fuel capsule with an impact velocity of 50 m/s onto a flat essentially unyielding surface. The impact target shall have a minimum mass of 50 times that of the test capsule. The surface shall be normal to the trajectory of the capsule. At the moment of impact either the capsule shall be oriented to in the position to sustain the maximum damage, or at least 50 impacts with random orientation of the capsule shall be performed. Separate capsules may be used for each impact.

Crush Test: The test shall be carried out by placing the fuel capsule between roughened steel jaws, each at least 2 cm thick normal to the direction of crushing and having a surface area which is large compared to the area of the capsule fitted to a press providing a load of 1000 kg. This test shall be carried out in one of three ways: (1) the capsule shall be oriented in the position in which it will sustain maximum damage, (2) the test shall be performed with the capsule gripped in every distinguishable stable orientation between the jaws of the press, (3) at least 50 tests with random orientation of the capsule shall be performed. This crush test shall be repeated after the temperature test below.

Temperature Test : The fuel capsule shall be maintained at a temperature of 800°C for a period of 30 minutes and then immediately plunged into a large volume of water at room temperature. For the purposes of this test, the internal pressure of the capsule shall be the maximum which could be achieved during its useful life.

Temperature Test followed by Crush Test: The fuel capsule shall be subjected to the temperature test as stated above followed by the crush test.

Temperature Test with high internal capsule pressure: The standard capsule was modified to allow bursting pressure measurements at 600°C, 1000°C, and 1300°C.

Cremation Temperature Testing: The pacemaker shall be maintained at 1300°C for 30 minutes in order to simulate the cremation of a human cadaver containing a cardiac pacemaker.

Corrosion Testing: A test shall be carried out in sea water with and without oxygen for a minimum period of one year.

Nuclear Powered Cardiac Pacemaker – Technical Data

Attachment C

Manufacturer	Activity	Pu-238 Enrichment	Pu-236 ppm	Cap 1	Cap 2	Cap 3	Pacemaker	Dose rates (mrem/hr)
Medtronic, Inc. Minneapolis, MN Laurens-Alcatel Model 9000	2.9 Ci PuO _{1.9} 0.160 g CIT-Alcatel	90% 88% Spg _{Theor}	0.26 - 0.63	Ta 6.5 mm OD x 7.0 mm TIG weld	Pt-20% Ir 8.9 mm OD x 9.6 mm min. 1 mm thk wall TIG weld	Ti - 1 mm wall 23 mm OD x 49 mm 42 g EB weld	Ti - 0.5 mm Wall thk 7 cm OD x 2.6 cm weight 170 grams SF AID-1.137	3.2 g 4.8 η will increase 20% over 10 yr
General Atomics San Diego, CA 92138	3 Ci 0.185 g PuN ₂ UKAEA Model Mark II			Hastalloy-C 1.0 mm walls 6.0 mm OD x 12.1 mm	1 mm gamma shield	.	SS 1 mm 17 mm OD x 40 mm	18 g 10 η γ dose rate will increase over 10 yr to 40 mrem/hr
General Atomics San Diego, CA 92138	3 Ci 0.185 g PuO ₂			TA-10W 5.1 mm OD x 12 mm 0.81 mm wall EB	SS 5.6 mm OD x 12.5 mm 0.25 mm wall EB	Ta 1 mm g shield 17 mm OD x 38 mm	SS 1 mm min.	17 mrem/hr g 18 mrem/hr η
ARCO Chemical Co. (formerly Perma Grain)	8 Ci PuO ₂ 0.420 g NU-5 Battery NUMEC	80% 105 -250 μ particles	<0.36	Ta-10W 1.0 mm walls TIG	Hastelloy-C 0.5 mm coated 25 microns Pt TIG	Ti 0.6 mm 8 .0 mm OD x 38 mm TIG thermopile cupron:trophel Ni-Cu:Ni-Cr	Ti 0.6 mm TIG 6x5x3.2 cm weight 112 grams	3.9 g 2.4 η will increase 30% over life
Biocontrol Technology, Inc. (formerly Coratomic, Inc.) Indiana, PA 15701	4.8 Ci 0.28 g	90% pressed & sintered 68% Spg _{Theor} spherical 4.0 mm OD	<0.36	Ta-10W sphere 3.2 mm ID x 3.9 mm OD TIG weld	Pt-10% Rh hemi-sphere 6.5 mm x 8 mm OD TIG weld	Ti tear drop shaped 18.2 mm OD x 29 mm welded vac seal + getter	Ti C-100 &C-101 4.70x5.97x1.93 cm wt. 61 grams	1.6 g 20 η will increase 35% over 20 yr USA/0383/S
Cordis (Telektronic, Accufix) Hialeah, FL Cordis Model 184A & 184B	2.8 Ci 0.22 g Oxide Hittman NB-200		< 0.3	Ta-10W 7.8 mm OD x 6.9 mm 1 mm wall thk. 1.6 mm end cap	Hastelloy C-276 8.6 OD x 7.6 mm 0.38 mm wall thk 0.38 mm end cap	Ti-4V 16.9 mm OD x 45.7 mm includes BiTe thermopile vac seal + getter	70 x 60x 20 cm 95 grams	660 n/s 4 mr/hr at battery
American Optical Md. 281343	2.8 Ci Hittman NB-200	80 % (min)	0.6	Ta-10W 7.8 mm OD x 6.9 mm 1 mm wall thk. 1.6 mm end cap TIG Weld	Hastalloy-C276 8.6 OD x 7.6 mm 0.38 mm wall 0.38 mm end cap TIG Weld	Ti-4V 16.9 mm OD x 45.7 mm Bi-Te Thermopile vac seal + getter	semi-oval 125 grams 71 mm x 20 mm	6.4 γ 0.7 η

